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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,624	07/25/2003	Takayuki Kohchi	026350-087	9637
21839	7590	10/07/2005	EXAMINER	
BUCHANAN INGERSOLL PC (INCLUDING BURNS, DOANE, SWECKER & MATHIS) POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			YU, GINA C	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/626,624

Applicant(s)

KOHCHI ET AL.

Examiner

Gina C. Yu

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 9-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>3/8/05, 7/25/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This application appears to be a division of Application No. 09/931,075, filed on August 17, 2001. A divisional application is a later application for a distinct or independent invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in an earlier or parent application. See MPEP § 201.06. As the result of the restriction requirement made by the examiner on September 10, 2002 during the prosecution of the parent application, composition claims were elected. In the present case, claims 9-18 are compositions claims, which are directed to the invention that applicants have already elected in the parent application. Thus, claims 9-18 are withdrawn from consideration in this divisional application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Okubo et al. (JP 9-241637-A, English Translation).

Okubo et al disclose in Table 1 that 0.01-20 mM of citrulline provides antioxidant effect. See Translation, [0086]-[0097]. The reference also discloses in paragraphs [0080]-[0084] that citrullin, along with epigallocatechin, is mixed and incorporated into pharmaceutical agents, food, and in cosmetics to improve the shelf-life of the products.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waugh (US 5874471).

Waugh discloses a method of using citrulline as an oral supplement. See Examples and Dietary Formulations in col. 10, line 40 – col. 17, line 53. See instant claims 1, 2, 7. The reference teaches that administration of citrulline, a precursor of L-arginine, is effective in increasing endogenous production for nitric oxide and managing atherosclerosis, which is “considered to be a free radical disease”. See col. 5, line 23 – col. 7, line 11. See also col. 7, lines 40 – 53 for the teaching that increasing L-arginine level in cell alleviates oxidative stress.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Okubu et al. in view of Ennen et al. (WO 95/15147).

While Okubu et al. teach that citrulline effectively provides antioxidant effect the reference does not mention the specific amount as required by the present claim. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 CCPA 1955).

Ennen et al. teach cosmetic composition comprising L-citrulline. See abstract. The reference teaches in p. 15, formulation 6 of the original document that 2.5 % of citrulline (MW 175.2) is used in a composition. Thus about 0.143 M, or 143 mM concentration of citrulline is present in the composition, meeting the present claims 2 and 3.

Given the teaching of the antioxidant efficacy of citrulline in cosmetics in Okubu et al., one of ordinary skill in the art would have been obviously motivated to look for a prior art such as Ennen et al., for a specific teaching on the amount of citrulline that is used to make a cosmetic composition. The skilled artisan would have had a reasonable expectation of successfully preserving the cosmetic composition from oxygen injury.

Conclusion

No claims are allowed.

Claims 1-8 are rejected.

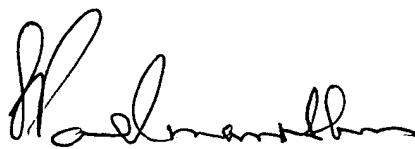
Claims 9-18 are withdrawn from consideration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605. The examiner can normally be reached on Monday through Friday, from 8:30 AM until 6:00 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu
Patent Examiner



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER